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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,343	09/18/2003	Megan Anne Diehl	A01341 US-3	7043

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EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
06/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,343	DIEHL ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 7-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3 and 7-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action

Claims 1, 3 and 7-12 are pending. No claim is allowed at this time. Amendments are entered.

Summary of this Office Action dated June 7th, 2007

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. 35 USC § 103(a) Rejection
5. Response to Remarks
6. Conclusion
7. Communication

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

1. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 3 and 7-12 rejected under 35 U.S.C. 103(a) as being unpatentable over ANTONI-ZIMMERMANN et al.[1] The reference teaches the synergistic combination of 2-methylisothiazoline and various other active biocidal substances which embraces Applicant's claimed invention. See the entire document especially abstract of the invention, lines 3-67 in column 2; lines 1-67 in column 3; lines 1-67 in column 4; examples and claims.

[1] US Patent 6,361788

The reference teaches a list of some active biocidal compounds, which includes presently claimed biocidal compound such as benzyl alcohol, (claim 8), sorbic acid, benzoic acid, phenoxy ethanol, (claim 1) and many others.

Instant claims differ from the reference in claiming different ratios of the components.

It would have been obvious to one skilled in the art to prepare additional beneficial compositions for inhibiting synergistically the growth of microorganisms by using the teaching of the prior art to combine 2-methylisothiazoline and one or two active biocidal component.

The ratio of the two components is a routine expectation for the one who is skilled in the art.

The motivation to prepare synergistic biocidal compositions and method of inhibiting microorganisms as presently claimed has been provided by the prior art.

SeeEx parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) where it was held that

"Use of materials in combination, each of which is known to function for intended purpose, is generally held to be prima facie obvious, and in instant case, use of combination of herbicides is so notoriously well known as to be capable of being taken by official notice; generalizations such as Colby formula are not particularly useful in determining whether synergism has been demonstrated, since formula inherently results in expectation of less than additive effect for combination of herbicides, since there is no evidence that such approach is considered valid by significant number of ordinarily skilled workers in relevant area of technology, and since it could be reasonably argued that in most cases, additive or better than additive results could be expected for combination of herbicides."

"There is no single, appropriate test for determining whether synergism has been demonstrated for chemical combination; rather, facts shown in each case must be analyzed to determine whether chosen method has clearly and convincingly demonstrated existence of synergism or unobvious result".

"Assuming arguendo that the differences in values presented are statistically significant, there is no evidence that they represent a true, practical advantage. In re Freeman, 474 F.2d 1318, 177 USPQ 139 (CCPA 1973); In re Klosak , 455 F.2d 1077, 173 USPQ 14 (CCPA 1972); In re D'Ancicco, 439 F.2d 1244, 169 USPQ 303 (CCPA 1971). Also, prescinding from the Colby formula test, which as we have already indicated is at best controversial and in our view probably invalid, there is no evidence that the differences are unexpected. In re Merck, 800 F.2d 1091, 231 USPQ 375 (Fed.Cir. 1986); In re Longi , 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985); In re Freeman, supra" .

Normally, change in temperature, concentration, or both, is not a patentable modification; however, such changes may impart patentability to a process if the ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed "critical" ranges, and applicant has burden of proving such criticality; even though applicant's modification results in great improvement and utility over prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art; more particularly, where the general conditions of the claim are disclosed in the prior art, it is not inventive to

discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233.

It is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937). In re Russell, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971).

It is a general rule that merely discovering and claiming a new benefit of an *old* process cannot render the process again patentable. Nor can patentability be found in differences in ranges recited in the claims. When the difference between the claimed invention and the prior art is some range or other variable within the claims, the applicant must show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range. In re Woodruff, 16 USPQ2d 1934.

Data in the Specification

The data presented in the specification was considered but was not found persuasive. It is unclear from the data presented in Tables 1-9 the synergism. Applicant is kindly requested to explain the data what was unexpected. Furthermore, the data presented covers the combination of 2-isothiazole and benzoic acid (Table 1), citric acid (Table 2), sorbic acid (Table 3), 1,2-dibromo-2,4-dicyclobutane (Table 4), 1,3-dimethylol-5,5-dimethylhydantion (Table 5), henoxyethanol (Table 6), zinc pyrithione

(Table 7), climbazole (Table 8), and benzyl alcohol (Table 9). The claimed combinations are much more than the data in the specification. The synergism of all the combination for the entire microorganism cannot be predicted.

The data presented is for certain organisms; the claimed invention is not limited to those organisms. Further, the synergistic combinations have been taught by the prior art. The synergism as claimed would have been expected for reasons cited above.

It has been decided by the courts that single species is seldom, if ever, sufficient to support a generic claim. *In re Shokal*, 242 F.2d 771, 113 U.S.P.Q. 283, 285 (C.C.P.A. 1957). See also, *In re Grimme*, 274 F.2d 949, 124 U.S.P.Q. 499, 501 (C.C.P.A. 1960) (the naming of a member of a genus or subgenus is not a proper basis for claiming the whole group).

Objective evidence of nonobviousness must be commensurate in scope with the scope of the claims. In re Tiffin, 171 USPQ 294. A showing limited to a single species can hardly be considered probative of the invention's nonobviousness in view of the breadth of the claims.

In absence of any criticality and/or unexpected results presently claimed invention would have been *prima facie* obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Remarks

- Arguments are found persuasive therefore double rejection over 11/265,654 is withdrawn. Other rejection is maintained because arguments are not found persuasive.
- Examiner respectfully disagree that claims cannot be obvious over the disclosure of the references, and the rejection should be withdrawn. Moreover, the reference does not disclose combinations comprising 2-methyl-3"isothiazolone and zinc pyrithione, climbazole or citric acid, as recited in claims 7, 8 and 11, respectively. It is not necessary to demonstrate synergy of the composition with respect to every possible organism. Examiner has shown that the combination of other active agents with 2-methyl-3 isothiazolone would have been obvious to one skilled in the art at the time invention was made.
- See Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) where it has been held that "Use of materials in combination, each of which is known to function for intended purpose, is generally held to be prima facie obvious, and in instant case, use of combination of herbicides is so notoriously well known as to be capable of being taken by official notice; generalizations such as Colby formula are not particularly useful in determining whether synergism has been

demonstrated, since formula inherently results in expectation of less than additive effect for combination of herbicides, since there is no evidence that such approach is considered valid by significant number of ordinarily skilled workers in relevant area of technology, and since it could be reasonably argued that in most cases, additive or better than additive results could be expected for combination of herbicides."

- "There is no single, appropriate test for determining whether synergism has been demonstrated for chemical combination; rather, facts shown in each case must be analyzed to determine whether chosen method has clearly and convincingly demonstrated existence of synergism or unobvious result".

- "Assuming arguendo that the differences in values presented are statistically significant, there is no evidence that they represent a true, practical advantage. In re Freeman, 474 F.2d 1318, 177 USPQ 139 (CCPA 1973); In re Klosak , 455 F.2d 1077, 173 USPQ 14 (CCPA 1972); In re D'Ancicco, 439 F.2d 1244, 169 USPQ 303 (CCPA 1971). Also, prescinding from the Colby formula test, which as we have already indicated is at best controversial and in our view probably invalid, there is no evidence that the differences are unexpected. In re Merck, 800 F.2d 1091, 231 USPQ 375 (Fed.Cir. 1986); In re Longi , 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985); In re Freeman, supra".

- See also Supreme Court KSR Decision No. 04-1350 (decided April 30, 2007).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Qazi

SABIHA QAZI, PH.D
PRIMARY EXAMINER